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VIA EMAIL AND FEDERAL EXPRESS

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Office of Counsel to the Inspector General
U.S. Department of Health and Human Services
Room 5227, Cohen Building
330 Independence Ave, S.W.
Washington, DC 20201

Re: Pfizer Inc.
Advisory Opinion Request No. R1225

Dear Mr. Kameen:

I am writing in response to your October 8, 2019 letter seeking additional information in support of the above-referenced advisory opinion request submitted by Pfizer Inc. ("Requestor"). We appreciate OIG's focus on this matter. As discussed during our prior calls, the patient access issues presented by the availability of Vyndaqel® (tafamidis meglumine) and Vyndamax™ (tafamidis) (collectively, "tafamidis" or the "Medications") are at an exigent stage. Moreover, we believe that a plain reading of the Anti-Kickback Statute ("AKS") and Beneficiary Inducement Statute ("BIS") compel an approval of the request, without a need to consider enforcement discretion factors. Before addressing the OIG's questions, we explain this threshold issue in more detail.

As you know, earlier this year, the U.S. Food and Drug Administration ("FDA") granted the Medications an accelerated approval to treat transthyretin amyloid cardiomyopathy ("ATTR-CM"). ATTR-CM is a rare, fatal disease. Left untreated, ATTR-CM inevitably progresses to heart failure and death—usually within three-to-five years of diagnosis. The Medications offer these patients new hope for a longer and better life, and may provide a bridge to future therapies. They also are the only FDA-approved drug treatment for ATTR-CM, with the prior alternative treatment—liver and/or heart transplants—costing more than $2 million. The Medications are thus a lower cost, less invasive alternative for ATTR-CM patients. But even though the Medications are otherwise accessible and cost substantially less than the only other viable treatment, Medicare's copay requirements put the Medications out of reach of many

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middle- and low-income Medicare patients—patients who have the same right to life-enhancing medicine as everyone else. The policy implications of Pfizer's request could not be more stark.

The issue presented is an urgent matter. Medicare patients are suffering the debilitating and fatal effects of ATTR-CM right now, yet many are unable to benefit from a breakthrough, available treatment—because they cannot afford their Medicare copays. The AKS and the BIS were not meant to prevent patients from accessing life-extending medications simply because those patients cannot afford to pay the copay that their insurers have imposed on them. And those statutes' fundamental concerns—that a company might induce prescribers and patients to choose one course of treatment over another by offering them something of value to change their treatment decisions—have no bearing here. Those concerns are not implicated where there is only one approved drug treatment available for this rare, debilitating, fatal disease and patients cannot afford their copays due the Medicare benefit design.

Congress recognized and understood these concerns. Precisely for the reasons presented here, the AKS and the BIS exempt copay waivers from the meaning of "remuneration" assuming the statutory conditions are met.[1] Importantly, the statutory exemption by its terms applies to copay waivers by any "person," a term the OIG has repeatedly found in many other contexts to ***include*** drug manufacturers,[2] and that takes

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[1] 42 U.S.C. § 1320a-7a(i)(6)(A); 42 C.F.R. § 1003.110.

[2] OIG has issued many advisory opinions holding that pharmaceutical companies are "persons" under the AKS and the BIS. *See* Advisory Opinion No. 19-02 (Jan. 29, 2019) (interpreting the word "person" in the BIS and the word "whoever" in the AKS to cover pharmaceutical manufacturers); Advisory Opinion No. 17-07 (Dec. 11, 2017) (same); Advisory Opinion No. 17-03 (Aug. 25, 2017) (same); Advisory Opinion No. 16-07 (June 27, 2016) (same); Advisory Opinion No. 15-11 (Aug. 12, 2015) (same); Advisory Opinion No. 14-05 (July 28, 2014) (same); Advisory Opinion No. 11-07 (June 8, 2011) (same); Advisory Opinion No. 09-08 (July 28, 2009); Advisory Opinion No. 08-05 (Feb. 22, 2008) (same); Advisory Opinion No. 08-04 (Feb. 12, 2008) (same); Advisory Opinion No. 07-04 (April 6, 2007); Advisory Opinion No. 06-14 (Aug. 15, 2014) (same); Advisory Opinion No. 03-3 (Feb. 12, 2003) (same); Advisory Opinion No. 02-13 (Oct. 4, 2002) (same); *see also* Advisory Opinion No. 08-05, at 7 n.6 (Feb. 22, 2008) ("[A]n offer of remuneration by a pharmaceutical manufacturer to a beneficiary to influence the beneficiary to select a particular physician would implicate the statute."); Advisory Opinion No. 07-04, at 6 n.9 (April 6, 2007) (explaining that pharmaceutical manufacturers fall within the meaning of "any person" in the BIS); Advisory Opinion No. 04-03, at 5 (June 1, 2004) ("[A]rrangements whereby a pharmaceutical company provides any form of remuneration to a physician, either directly or indirectly through a conduit entity or arrangement, potentially implicate the anti-kickback statute and must be carefully scrutinized."). OIG has also issued guidance about AKS and BIS compliance to pharmaceutical manufacturers that assumes or expressly states that the AKS and the BIS apply to them. *See* Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014); Publication of OIG Special Advisory Bulletin on Patient Assistance

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its meaning from the Dictionary Act, 1 U.S.C. § 1, which defines persons to include corporations.[3] If pharmaceutical manufacturers are "persons" pursuant to some provisions of the AKS and the BIS, then they are "persons" for purposes of the copay waiver provision as well: "A term appearing in several places in a statutory text is generally read the same way each time it appears."[4] Thus, a copay waiver under the circumstances presented in Requestor's advisory opinion request does not violate the AKS or the BIS by their own plain terms. The copay waiver exception is an "important exception" that allows "suppliers … [to] forgive the copayment in consideration of a particular patient's financial hardship."[5]

Requestor has designed its proposed Copay Assistance Program to fit within the four corners of that copay waiver exception: (1) Requestor's proposed Copay Assistance Program would not be offered as part of any advertisement or solicitation; (2) Requestor would not "routinely" make such waivers; and (3) Requestor would provide waivers only after determining in good faith that a patient is in financial need. Indeed, to the degree OIG has any concerns that Requestor's proposed Program might not fit within the waiver exception, Requestor is willing to work with OIG to adjust the Program to address such concerns.

In short, the threshold issue in this request is not a matter of enforcement discretion. It is a matter of statutory interpretation and simply asks OIG to apply the statute as written to the facts as presented.[6] This can and should be done quickly, without the need for a long back and forth process or a referral to the Centers for Medicare & Medicaid Services ("CMS"). We request that OIG act on this part of the request within

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Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623 (Nov. 22, 2005); OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23,731 (May 5, 2003). The Department of Justice has taken the position in federal court that the word "person" in the AKS must be construed according to the Dictionary Act, 1 U.S.C. § 1, which states that unless otherwise specified, "the words 'person' and 'whoever' [in federal statutes] include corporations." *See* Memorandum of Law of the United States in Opposition to Novartis's Motion to Compel, *United States v. Novartis Pharmaceuticals Corp.*, 2014 WL 5590895 (S.D.N.Y. Sept. 29, 2014) (quoting 1 U.S.C. § 1).

[3] *See* 1 U.S.C. § 1; *see Burwell v. Hobby Lobby Stores, Inc.*, 573 U.S. 682, 707-08 (2014) (explaining that the Dictionary Act applies to the Religious Freedom Restoration Act (RFRA) and thus corporations are "persons" under RFRA).

[4] *Ratzlaf v. United States*, 510 U.S. 135, 143 (1994). "In all but the most unusual situations, a single use of a statutory phrase must have a fixed meaning …. We therefore avoid interpretations that would attribute different meanings to the same phrase." *Cochise Consultancy, Inc. v. United States ex rel. Hunt*, 139 S. Ct. 1507, 1512 (2019) (citations and quotation marks omitted).

[5] *See Publication of OIG Special Fraud Alerts*, 59 Fed. Reg. 65,372, 65,375 (Dec. 19, 1994).

[6] *La. Pub. Serv. Comm'n v. FCC*, 476 U.S. 355, 374 (1986) (explaining that an agency has "literally … no power to act … unless and until Congress confers power upon it").

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the 60-day timeframe set out in the statute for advisory opinions, so that Medicare patients can access these important, life-extending Medications.

We respond to each of the questions in your October 8, 2019 letter below. For convenience, the following is a brief summary of the Copay Assistance Program and how it would operate (each of these points is explained in more detail in response to your specific questions):

- Only Medicare patients with coverage for the Medications would be eligible to participate in the program. Other patient eligibility criteria would include:
  - Medication is prescribed for the treatment of ATTR-CM
  - Patient is a U.S. resident
  - Patient's household income is between 300% and 800% of the federal poverty limit ("FPL")

  Requestor would determine patient eligibility in a uniform and consistent manner.

- Medicare patients would learn about the program from Requestor's patient support hub ("VyndaLink" or the "Hub") only after such patients have been prescribed one of the Medications, have enrolled in the Hub, and the Hub has verified that the patients have Medicare coverage for the Medication. Requestor would not offer this copay assistance as part of any advertisement or solicitation for the Medications.

- The Hub would verify patient eligibility and enroll eligible patients in the program. Requestor would engage a copay program administration vendor to administer certain aspects of the program.

- Enrolled patients should be able to access the copay assistance from any of the specialty pharmacies within Requestor's defined pharmacy network for the Medications.

- Enrolled patients would pay $35 out of pocket at the point of sale. The program would cover the balance of the patient's copay obligation.

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- Medicare patients would continue to be eligible to participate in Requestor's free drug program if they meet that program's eligibility criteria.

- The program would provide assistance for out-of-pocket costs only for the Medications, not for other prescription drugs used by ATTR-CM patients in connection with managing their disease.

1. Please detail how patients would learn about or become aware of the existence of Requestor's Copay Assistance Program for these Medications.

Consistent with the copay waiver exception of the BIS, Requestor would not offer this copay assistance as part of any advertisement or solicitation for the Medications. Requestor would limit communications about the Copay Assistance Program to certain non-promotional channels, as described below. Requestor's aim would be to inform Medicare patients already prescribed the Medications that copay assistance is available. Requestor would not seek to influence patients to ask their physicians to prescribe the Medications.

Medicare patients would learn about or become aware of the Copay Assistance Program from the VyndaLink Hub. The Hub would provide information to a Medicare patient regarding the program only after that patient has enrolled in the Hub and the Hub has confirmed that the patient has coverage under a Medicare plan for the Medications. In such cases, VyndaLink would provide the following information:

- Patient eligibility requirements,
- Patient out-of-pocket contribution ($35 per month),
- Other applicable terms and conditions, and
- The process for enrollment in the program

Other than providing the information described above following a patient's benefits investigation, the Hub would not conduct any proactive outreach to patients about the program.

Requestor's field-based personnel (including sales representatives) would not be permitted to communicate with patients, physicians or any other third parties about the Copay Assistance Program. Requestor would train its sales representatives and other field-based personnel: (i) not to discuss the program and (ii) how to respond to unsolicited questions about support for Medicare beneficiaries (i.e., patients should contact the Hub to learn about potential financial assistance options). Moreover,

Requestor would not distribute any written materials to physicians to share with their patients that would describe or mention this program.

Finally, neither Requestor's website for the Medications nor the VyndaLink website would include any information about the Copay Assistance Program. The brand website would instruct patients who have been prescribed the medication to contact VyndaLink to learn about potential financial assistance options, and would include a link to the VyndaLink website. The VyndaLink website would direct patients who have been prescribed the Medications to contact the Hub to learn about potential financial assistance options, and would not include information about this Copay Program on the website itself.

2. Please detail how prescribers would learn about or become aware of the existence of Requestor's Copay Assistance Program for these Medications.

A prescriber would learn about the Copay Assistance Program from the VyndaLink Hub only if the prescriber contacts the Hub and requests information about financial support for a Medicare patient enrolled in VyndaLink. The Hub would not conduct any proactive outreach to prescribers or their offices about the program.

As described above in response to question 1, neither the VyndaLink website nor the website for the Medications would describe the program, and sales representatives and other field-based personnel would not be permitted to communicate with prescribers or their office staff about this Copay Assistance Program. Requestor would train its sales representatives and other field-based personnel not to discuss the program, as well as how to respond to unsolicited questions about support for Medicare beneficiaries.[7]

3. Explain what, if any, talking points, education, or other materials Requestor would furnish to prescribers to instruct them regarding how to communicate with patients regarding the cost of the Medications and any available support from the Requestor.

Requestor would not provide talking points to prescribers or instruct prescribers on how to talk to their patients. Requestor currently is developing a brochure about the VyndaLink Hub for patients that sales representatives would provide to physicians to share with patients after prescribing a Medication. Neither this proposed brochure nor

[7] If a prescriber were to ask a sales representative or other field-based personnel about potential financial support options for Medicare patients, the sales representative or other field-based personnel would refer the prescriber to the Hub for information.

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any other written materials provided by the Requestor would mention the Copay Assistance Program.

Requestor currently provides information to prescribers about patient support options for patients who have been prescribed either Medication in the following non-promotional ways:

- Requestor's Field Reimbursement Managers ("FRMs") communicate to prescribers and office staff about the types of financial support options that are available for commercially insured patients, Medicare, and other Federal health care program beneficiaries and uninsured patients. FRMs are subject matter experts on reimbursement, access, and coverage issues affecting Requestor's products. They educate physicians and their staff on these topics to facilitate appropriate patient access to prescribed Requestor products. FRMs do not promote the Medications or any other of Requestor's products, and do not receive incentive compensation. FRMs would not discuss the Copay Assistance Program with prescribers or office staff. If an FRM received a question about financial assistance for Medicare beneficiaries, the FRM would refer the prescriber to the Hub.

- Requestor's sales representatives provide prescribers with a written brochure that describes VyndaLink and the patient support that the Hub provides. Requestor would not modify this brochure to include any information about this Copay Assistance Program.

Requestor has trained its sales representatives and FRMs to refer physicians to VyndaLink if they receive questions from prescribers about the cost of the Medications and/or financial support for patients. Furthermore, Requestor trains the sales representatives not to promote VyndaLink or any patient support offerings as a reason for physicians to prescribe the Medications.

After a physician prescribes a Medication for a patient and enrolls the patient in VyndaLink, the Hub conducts a benefits verification to determine the patient's insurance coverage for the Medication. The Hub communicates the results of the benefits verification to the prescriber's office in writing and to the patient by telephone. Currently, the Hub informs all commercially insured patients with coverage for a Medication about Requestor's existing copay assistance program for commercial

patients.[8] If a patient or physician's office requests information about other available financial support—either when the Hub communicates the results of the benefits verification or by noting this request on the VyndaLink patient enrollment form—the Hub provides that information.

3.a Please detail the content of such talking points, education, or other materials, and whether any guidance regarding communications would vary based on the existence or type of the patient's insurance coverage.

As explained above, Requestor does not furnish talking points to prescribers. The VyndaLink brochure for health care professionals describes currently available patient support programs. There is only one brochure, which does not vary based on the existence or type of a patient's insurance coverage. Where applicable, the brochure notes whether eligibility for a program is limited based on the existence or type of a patient's insurance (e.g., the existing copay assistance program is limited to patients with commercial insurance). Requestor would not add a description of this Copay Assistance Program to this brochure.

Similarly, Requestor's FRMs currently describe to physicians and their office staff the patient support offerings available through VyndaLink. The FRMs' communications do not vary based on the existence or type of a patient's insurance, except for clarifying whether a particular offering applies only to patients with a particular insurance type (e.g., Medicare LIS is available only to Medicare beneficiaries; Requestor's existing copay assistance program is available only to commercially-insured patients). Patients and/or prescribers must contact the Hub and enroll the patient in VyndaLink for a determination of whether the patient is eligible for any particular financial support.

Following a benefits investigation for a specific patient enrolled in VyndaLink, the Hub provides information on the patient's insurance coverage and out-of-pocket obligations for the Medications to the patient and the prescriber. That information varies based on the patient's actual insurance. For patients with commercial insurance, the Hub provides information about Requestor's existing copay assistance program. After Requestor launches this Copay Assistance Program, the Hub would inform Medicare beneficiaries with coverage for the Medications about the availability of this program.

[8] After Requestor launches the proposed new Copay Assistance Program, the Hub similarly would inform all Medicare beneficiaries with coverage for a Medication about this Copay Assistance Program.

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4. In the development and execution of the Copay Assistance Program, would Requestor use any sort of intermediary that operates between Requestor, prescribers, specialty and other pharmacies, distributors, health plans, and patients, such as a referral hub, a reimbursement hub, a benefits investigations hub, or other third party acting on Requestor's behalf? If so, please describe how such intermediary or intermediaries would support or facilitate the Copay Assistance Program.

Yes, the VyndaLink Hub would support the Copay Assistance Program. As described above, the Hub would provide information about the program to Medicare patients enrolled in VyndaLink and their prescribers if the patients' Medicare plans cover the Medications. In addition, the Hub would evaluate patient eligibility for the Copay Assistance Program based on information that the patient and the prescriber include on the VyndaLink patient enrollment form. Specifically, the Hub would verify that the patient: (i) has Medicare coverage for one of the Medications, (ii) has been prescribed the Medication for the treatment of ATTR-CM, (iii) is a U.S. resident, and (iv) meets the program criteria for financial need.

The VyndaLink enrollment form currently requests patient financial information to allow the Hub to evaluate eligibility for financial support options. In the event a Medicare patient did not include financial information on the form at the time of enrollment, the Hub would ask the patient to provide that information before the Hub would evaluate the patient's eligibility for the Copay Assistance Program. Similarly, the enrollment form requests the prescriber to check a box to confirm that he or she has prescribed the Medication for the treatment of ATTR-CM. If the prescriber did not check the box that verifies on-label treatment, the Hub would ask the prescriber to confirm the diagnosis before the Hub would evaluate the patient's eligibility for the Copay Assistance Program.

Finally, if the patient meets all eligibility requirements, the Hub would communicate patient enrollment in the Copay Assistance Program to the patient, to the patient's prescriber (upon the prescriber's request) and to the patient's specialty pharmacy.

Requestor also would contract with a third-party, copay program administration vendor to perform the following activities related to the Copay Assistance Program:

(1) Complete patient enrollment by activating a physical copay card and/or issuing a personal identification number ("PIN") that the patient would use to

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receive the assistance at the time the patient purchases the Medication from a specialty pharmacy;

(2) Process copay card redemptions as they occur at specialty pharmacies;

(3) Reimburse specialty pharmacies for the patient out-of-pocket costs covered by the program; and

(4) Provide data reports to Requestor related to program activity. These reports would not include any patient identifiable information. Information would include the number of redemptions and amounts of copay assistance provided on a transactional basis.

The copay program administration vendor would not communicate directly with prescribers or patients enrolled in the program.

Requestor's contract with this vendor would be structured in accordance with the personal services safe harbor. Specifically: (i) all services that the vendor would perform would be described in the contract, (ii) Requestor would pay fair market value fees for each service performed, (iii) the service fees would not take into account the volume or value of any referrals or business otherwise generated between the parties for which payment may be made in whole or in part under any federal health care program, (iv) if possible, the aggregate compensation paid to the vendor over the term of the agreement would be set in advance, and (v) the aggregate services would not exceed those which are reasonably necessary to administer the program).

4.a Please detail how patients would learn about or become aware of the "patient support hub" referenced in footnote 30.

Requestor informs patients and physicians about the VyndaLink patient support hub in a variety of ways. Requestor's website for the Medications includes a link to the VyndaLink website, with the following simple statement: "VyndaLink; Support for your treatment journey."[9] The VyndaLink website describes the different types of support currently available to patients who have been prescribed the medications and directs patients to contact the Hub for more information. The VyndaLink website also includes the patient enrollment form for the Hub.

[9] Requestor may add additional information about VyndaLink to the brand website in the future.

Patients also may learn about VyndaLink from their prescribing physicians. Requestor's sales representatives and FRMs inform prescribers about VyndaLink during face-to-face visits and via written brochures for health care professionals. When they receive questions from a prescriber or office, sales representatives and FRMs also may share information with physician offices about VyndaLink via electronic mail communications. As noted above, Requestor currently is developing a patient brochure about VyndaLink that sales representatives would provide to physicians to share with patients after physicians prescribe a Medication for such patients.

Finally, Requestor's patient affairs liaisons ("PALs") may reactively provide information to patients about VyndaLink during their attendance at consumer events, such as Amyloidosis Support Group meetings. PALs are field-based, non-promotional personnel who serve as educational resources for both local advocacy groups and individual patients and caregivers. The PALs' primary function is to engage with local advocacy and patient groups to understand their goals, objectives and needs. PALs may staff exhibits and displays at patient meetings and conferences, as well as educate patients and their caregivers on disease awareness and management. During attendance at consumer events, PALs may respond to questions from patients about the availability of the VyndaLink Hub for patients prescribed the Medications. The PALs refer patients to the Hub for any specific questions about their coverage for the Medications and their eligibility for specific patient support programs. PALs would not be permitted to speak about the Copay Assistance Program with patients or other third parties.

4.b Is the "patient support hub" operated by a third party?

Yes, the Hub is operated by a third-party vendor pursuant to a written service agreement. The service agreement is structured in accordance with the personal services safe harbor.

4.c Please provide additional information about the operations of the "patient support hub" and the information available to patients through that hub.

The VyndaLink Hub provides support for patients who have been prescribed one of the Medications. To access this support, patients first must enroll in the Hub programs. Both the patient and the prescriber must complete and sign the patient enrollment form. The prescriber must provide prescription information on the enrollment form and must confirm that he or she has prescribed one of the Medications for the treatment of ATTR-CM (by checking a box on the form). In addition, the prescriber must certify that he or she has made an independent judgment that the Medication is medically necessary for the patient and that all information provided on the form is

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accurate. If a patient seeks financial assistance to access his or her prescribed Medication, the patient must provide specific financial information and documentation of the patient's annual household income (such as a federal tax return or W-2).

Once a patient is enrolled in VyndaLink, the Hub performs the following activities:

- Conducts a benefits verification to determine the patient's insurance coverage for the prescribed Medication, including out-of-pocket costs and payer coverage requirements. The Hub then informs the patient and the prescriber's office of the patient's coverage and whether the insurance plan requires a prior authorization before the plan will cover the Medication.

- Identifies specialty pharmacies at which the patient may obtain the Medication, based on the patient's insurance coverage. The Medications are available through various specialty pharmacies within Requestor's defined distribution network. If the patient's insurance plan allows the patient to obtain the Medications at more than one specialty pharmacy, the Hub will ask the patient whether he or she has a preference. If the patient does not express a preference, the Hub transfers the prescription to an applicable specialty pharmacy using an objective, round robin process. After the Hub transfers a patient's prescription to a specialty pharmacy, the Hub may contact the pharmacy to verify whether the patient received the Medication.

- Identifies financial support options (for patients who seek financial assistance) by conducting alternative funding research. The Hub researches patient eligibility under Requestor's financial support programs (such as copay assistance programs) and government programs (such as Medicare LIS), and determines whether there are any applicable independent, third-party charity programs that may be able to assist. The Hub notifies patients of the outcomes of such research. If a patient is eligible to participate in one of Requestor's financial support programs, the Hub facilitates enrollment in such program. The Hub does not enroll patients in any government programs or independent, third-party charity programs. The Hub simply notifies patients of the existence of such programs and provides information to allow the patient to contact the programs.

- Evaluates patient eligibility for Requestor's free drug program (for patients who are not eligible for any other available internal or external financial support programs). The Hub enrolls eligible patients in the free drug program and facilitates delivery of the Medications via the free drug program specialty

pharmacy, which is operated by a third-party vendor. This pharmacy is not within Requestor's defined specialty pharmacy network for the Medications and does not dispense the Medications to patients outside of the free drug program.

- Provides information to patients about the VyndaLink Patient Support Navigator Program ("Patient Navigator Program"). A patient that opts in to the Patient Navigator Program can receive information about third-party resources, such as relevant patient advocacy groups, that may provide additional support, such as patient education, counseling and social support and transportation and lodging assistance.[10] The patient is assigned a patient navigator, who is an employee of the Hub and who periodically contacts the patient to determine if he or she needs information about accessing available support. The Patient Navigator Program does not provide information about financial support for the Medications. Patients may opt out of the Patient Navigator Program at any time.

5. What information and documentation would Requestor require prescribers to send to Requestor, or a third party acting on behalf of Requestor, when a patient is directed to the Copay Assistance Program?

If a patient were to contact VyndaLink about the Copay Assistance Program, the Hub first would review the patient's enrollment form to determine whether the form includes all information necessary for the Hub to evaluate patient eligibility (i.e., patient address, insurance information, diagnosis code and confirmation by the prescriber that the prescription is for the treatment of ATTR-CM, and patient financial information). If the patient enrollment form does not include all required information, then the Hub would contact the patient and/or prescriber to collect any missing information (including proof of income). If the patient enrollment form contains all required information, the Hub would not require prescribers or patients to send any additional information.

6. Would Requestor require patients to use a particular specialty pharmacy for acquiring the Medications if they are supported by the Copay Assistance Program?

Eligible patients who enroll in the Copay Assistance Program should be able to access the assistance at any specialty pharmacy that is part of Requestor's defined specialty pharmacy network for the Medications. Requestor has not yet engaged a copay program administration vendor or discussed the proposed program with any of its

[10] The patient navigator provides contact information to allow the patient to contact these third-party resources. The patient navigator does not contact the third-party resources on behalf of the patient or caregiver.

network specialty pharmacies. Consequently, Requestor does not yet have complete information about the logistics for providing access to the program through all of its network specialty pharmacies. Nevertheless, Requestor does not foresee any insurmountable obstacles.

If the patient's Medicare plan requires that the patient use a particular specialty pharmacy (a "Payer-Mandated Pharmacy") and that pharmacy is part of Requestor's defined specialty pharmacy network, then the patient would be able to access the copay assistance from that specialty pharmacy. If the Payer-Mandated Pharmacy is outside of Requestor's network, then the Hub would send the prescription either to the patient's preferred in-network specialty pharmacy or to one of the in-network specialty pharmacies using an objective, round robin process. The specialty pharmacy that receives the prescription would seek a "Letter of Agreement" from the Payer-Mandated Pharmacy to allow the network specialty pharmacy to dispense the medication and be reimbursed by the payer. This is standard practice for all defined specialty pharmacy networks. Nevertheless, Requestor anticipates that these instances will be rare because Requestor's defined specialty pharmacy network covers the majority of patients whose payers mandate use of specific specialty pharmacies.

7. What information would be communicated by Requestor, or a third party acting on Requestor' s behalf, to the prescriber or pharmacy about the decision to grant assistance to a patient?

After the Hub evaluates the patient's eligibility for the Copay Assistance Program, the Hub would notify the patient only if he or she has been approved for enrollment. The Hub would notify the prescriber of the approval only if the prescriber were to request a status update. The Hub would notify the patient and/or the prescriber of a denial only if the patient or prescriber were to request that information.

For patients who are enrolled in the program, either the Hub or the copay program administration vendor would notify the patient of his or her program PIN. In addition, the Hub would: (i) communicate the enrollment to the specialty pharmacy from which the patient will receive the Medication, along with instructions on how to adjudicate the copay assistance, or (ii) instruct the patient on what to communicate to the pharmacy to access the assistance.

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8. Would the Copay Assistance Program only be open to Federal health care program beneficiaries?

The Copay Assistance Program would be open only to Medicare beneficiaries. Requestor currently offers a co-pay assistance program to patients with commercial insurance that covers the Medications. This program allows eligible patients to pay as little as $0 per month for the Medications (up to a prespecified annual cap) and does not have any financial need requirement. Patients enrolled in any state or federally-funded insurance program (including without limitation Medicare, Medicaid and Veteran Affairs/TRICARE) are not eligible to participate in the existing program.

Requestor desires to offer the proposed Copay Assistance Program specifically to Medicare beneficiaries because they are not eligible to participate in the existing program and there are limited external financial support options for these patients. Other Federal health care program beneficiaries, such as Medicaid beneficiaries, do not experience the same out-of-pocket cost burdens as Medicare beneficiaries; therefore, Requestor does not plan to offer the program to other Federal health care program beneficiaries.

9. Requestor mentions its existing "free drug program." Does Requestor plan to offer the Medications for free to any Federal health care program beneficiaries under its existing free drug program?

Yes, Requestor currently offers, and plans to continue to offer, the Medications for free to Federal healthcare program beneficiaries who meet the eligibility criteria described in response to the next question.

9.a If so, what, if any, criteria would apply to Federal health care program beneficiaries seeking free Medication through the free drug program?

The following eligibility criteria currently apply for all patients who apply for assistance from Requestor's free drug program, including Federal health care program beneficiaries:

- U.S. residency
- Valid prescription for the prescribed Medication from a health care professional licensed in the United States or a U.S. territory
- Patient is uninsured or underinsured (i.e., their prescription drug plan does not cover the Medication or the patient cannot afford their copay/coinsurance)
- Demonstrated financial need (income of up to 500% of the Federal Poverty Limit (FPL))

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Requestor's free drug program is intended to serve as a safety net for patients that are not eligible for any other financial assistance. Therefore, before any patient can enroll in the free drug program, the Hub researches potential alternative funding sources (*e.g.* Requestor's copay assistance program, Medicare LIS, and independent, charitable copay foundations). After Requestor launches the Copay Assistance Program, the Hub would include this program as part of the alternative funding research.

If the Hub determines that a patient is not eligible for any available alternative funding sources and meets the eligibility requirements of Requestor's free drug program, then the patient may enroll in the free drug program. Federal health care beneficiaries who enroll in the free drug program are enrolled for the duration of the calendar year. Such patients may apply to re-enroll for subsequent calendar years.

10. Please detail any interaction between Requestor's existing free drug program and the Copay Assistance Program. In particular:

10.a Would Federal health care program beneficiaries who seek the Medications under the free drug program be redirected to the Copay Assistance Program?

As described above, when a patient enrolls in VyndaLink, the Hub conducts a benefits investigation and an alternative funding search to determine whether the patient is eligible to receive financial support from any available programs (including programs sponsored by Requestor and programs sponsored by the government or independent third parties). The Hub requires patients to seek assistance from such other programs before patients may enroll in Requestor's free drug program. Requestor's free drug program is intended to serve as a safety-net to allow financially-needy patients without other alternatives to access their Medications.

Once the Copay Assistance Program becomes available, the Hub would require eligible Medicare patients, who are not enrolled in the free drug program,[11] to enroll in the Copay Assistance Program. If a Medicare patient demonstrates that he or she cannot afford the $35 cost-sharing requirement of the Copay Assistance Program, and the

[11] Medicare beneficiaries who qualify for the free drug program are enrolled for the remainder of the calendar year. Such patients must re-enroll for the program for each following calendar year. Patients who are eligible for the Copay Assistance Program would be directed to that program in future years, unless they are unable to pay the $35 required cost-sharing amount and continue to have income at or below 500% of the FPL.

patient's household income is at or below 500% of the FPL, then such patient would be able to apply for the free drug program.

10.b Would Federal health care program beneficiaries be denied Medications under the free drug program based on criteria that differs from patients without insurance or with commercial insurance?

No, the Hub would continue to apply the same eligibility criteria to applications by Federal health care program beneficiaries that it would apply to patients with commercial insurance or without any insurance. In all cases, patients must not be able to receive assistance from an alternative funding option (such as a Pfizer copay assistance program, a government program (like Medicare LIS) or an independent charitable foundation). This is the current practice, and the practice would not change after Requestor launches the Copay Assistance Program.

10.c Would Requestor otherwise take into account a patient's insurance or insurance status in making eligibility determinations for, or as between, the Copay Assistance Program and the free drug program for purposes of the Medications?

No, the Hub would not take into account the type of insurance that a patient has in making an eligibility determination for the free drug program. Today, the Hub evaluates whether a patient has coverage for the Medications under his/her existing insurance plan and whether the patient has sufficient coverage (i.e., can the patient afford the copays, co-insurance, and any other out-of-pocket costs). This practice would not change with the introduction of the Copay Assistance Program.

With respect to the Copay Assistance Program, the Hub would verify whether the patient is a Medicare beneficiary (as only Medicare beneficiaries would be eligible for this program). In addition, the Hub would take into account whether the patient's Medicare plan covers the Medications, as the program would provide assistance with copays and coinsurance.

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11. Would the Copay Assistance Program provide support for the other medical needs of patients diagnosed with ATTR-CM, including all prescription drugs used by the patient in connection with managing the disease, treating symptoms of the disease, or treating pain and other side effects of the disease?

No, the Copay Assistance Program would provide assistance only for out-of-pocket costs for the Medications. As we have previously explained, the Copay Assistance Program is structured in accordance with the statutory and regulatory exception to prohibited "remuneration" that allows for forgiveness of the copayment due for a product or service in consideration of a patient's financial hardship. These exceptions do not require (or authorize) companies to waive copayments for products or services provided by others.

11a. Would the Copay Assistance Program support qualifying ATTR-CM patients' other medical needs regardless of whether the patients are using the Medications?

No, the Copay Assistance Program would be limited to providing copay assistance for the Medications for the reasons given in response to Question 11.

12. Would the Copay Assistance Program support any other drugs or therapies approved by the Food and Drug Administration to treat or manage ATTR-CM and its symptoms and side effects, including drugs and therapies of a competitor that exist now or may exist in the future? If so, please provide detailed information regarding what other drugs or therapies the Copay Assistance Program would support.

No, the Copay Assistance Program is limited to providing copay assistance for the Medications for the reasons given in response to Question 11.

13. Requestor states on page 12 of its Request that the Medications are "targeted to a Medicare population." What does this statement mean, and why does Requestor target a "Medicare population" with these Medications?

This statement was not meant to imply that the Medications were intentionally targeted at the Medicare population, but rather to make the point that, due to the natural history of ATTR-CM, the majority of patients who may be prescribed the Medications will be Medicare recipients.

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As discussed in our original request, ATTR-CM can be an inherited condition ("hereditary" form), or it can occur spontaneously in elderly patients without a known predisposition ("wild type" form). In the United States, the hereditary version most commonly affects African-American men, who typically first experience symptoms after age 50.[12] The wild-type form is believed to be more common and is thought to affect approximately 1% of men over 80, with symptoms typically beginning around age 65.[13] Given the typical age of onset of the disease, it is likely that Medicare will cover a substantial portion of the ATTR-CM patient population that may benefit from the Medications.

14. Requestor refers to "two possible solutions" on page 13. Please confirm that R1225 describes only one proposed arrangement involving the Copay Assistance Program.

This request describes only one proposed arrangement involving the Copay Assistance Program. The reference on page 13 is a typographical error. Please disregard the reference to two possible solutions.

15. Please confirm that Requestor will determine eligibility according to a reasonable, verifiable, and uniform measure of financial need that would be applied in a consistent manner.

We confirm that Requestor would determine patient eligibility according to a reasonable, verifiable and uniform measure of financial need that would be applied in a consistent manner.

15.a Please detail the objective criteria that will be applied uniformly and consistently as part of the financial need determination applied to applicants to the Copay Assistance Program.

Requestor would require that patients have a household income between 300% and 800% of the FPL. Under the Medicare Part D benefit, a patient must pay approximately $13,000 in annual out-of-pocket costs for the Medications. This expense is on top of other expenses these patients typically incur in connection with their disease and other comorbidities. Therefore, Medicare patients with above average incomes still may have significant difficulty affording their out-of-pocket costs for the Medications.

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[12] *See* https://www.heart.org/-/media/files/health-topics/answers-by-heart/abh_what-is-attrcm_v2_a.pdf?la=en&hash=FD4B12B23CF6CD8BF3691373CA29B869840A483D.
[13] *See Id.* and http://amyloidosis.org/facts/wild-type/#faqs.

Medicare patients with incomes below 150% of the FPL would be eligible for the Medicare Low Income Subsidy, and patients with incomes of up to 500% of the FPL would continue to be eligible for Requestor's free drug program.[14] Patients would be required to provide proof of income to allow the Hub to verify patient eligibility.

As noted, the other eligibility criteria for the Copay Assistance Program would include: (i) enrollment in a Medicare Part D or Medicare Advantage plan, (ii) a Medication that is prescribed for the treatment of ATTR-CM, and (iii) patient is a U.S. resident.

16. Please provide additional information regarding how the Copay Assistance Program would operate in accordance with the corporate integrity agreement executed by Requestor and HHS-OIG on May 23, 2018.

Requestor's Corporate Integrity Agreement ("CIA") does not prohibit Requestor from providing a copay card to a Federal health care program beneficiary. The CIA requires Requestor to maintain policies and procedures regarding co-pay cards and coupons that are "designed to ensure that Requestor's operation of or participation in such programs complies with all applicable Federal health care program requirements … [and that they are also] … designed to ensure that [Requestor's] operation of or participation in any such [program] complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs, including but not limited to, the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (Sept. 2014)." A Copay Assistance Program that OIG has confirmed is lawful in an Advisory Opinion "complies with all guidance issued by OIG relating to assistance provided to patients by pharmaceutical manufacturers to reduce or eliminate the cost of copayments for drugs."

In any event, no laws or existing OIG guidance preclude Requester's proposed program. Neither the relevant Federal health care program requirement, i.e., the Anti-Kickback Statute, nor the OIG's Special Advisory Bulletin on Pharmaceutical Manufacturer Copayment Coupons (the "Bulletin") prohibit manufacturers from providing a copayment card to a Federal health care program beneficiary.

[14] Patients with incomes between 300% and 500% of FPL would be eligible for both the free drug program and the Copay Assistance Program. Because the free drug program is a program of last resort, patients first would be required to enroll in the Copay Assistance Program, unless they demonstrate that they cannot afford the $35 cost-sharing requirement of the Copay Assistance Program. Requestor may choose to increase or decrease the FPL requirement for the free drug program in the future, based on new information about patient need.

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As Requestor's submission explained, the Copay Assistance Program is consistent with the Anti-Kickback Statute and falls squarely within the statutory exception for unadvertised co-pay waivers. And while the OIG has expressed its view in the Bulletin that pharmaceutical manufacturers should not provide coupons to Medicare patients and examined the methods manufacturers use to exclude Federal health care program beneficiaries from such programs, the Bulletin does not state that it is illegal for manufacturers to do so. For example, the OIG states in the Bulletin that:

> While copayment coupons provide an immediate financial benefit to beneficiaries, they ultimately can harm both Federal health care programs and their beneficiaries. The availability of a coupon may cause physicians and beneficiaries to choose an expensive brand-name drug when a less expensive and equally effective generic or other alternative is available. When consumers are relieved of copayment obligations, manufacturers are relieved of a market constraint on drug prices. Excessive costs to Federal programs are among the harms that the anti-kickback statute is intended to prevent. (emphasis added) (footnote omitted)

Requestor's submission goes into great detail to explain why the potential concerns articulated in the Bulletin are not applicable with the Copay Assistance Program. For all the reasons discussed in the submission, the Copay Assistance Program is consistent with applicable law, OIG guidance and, accordingly the CIA.

* * *

We hope this information has been helpful to you. For the reasons described, this Advisory Opinion as a threshold matter presents a clear question of statutory interpretation that can be resolved as a matter of law. Given the exigent circumstances that the Copay Assistance Program is intended to address, we respectfully request that OIG resolve that threshold question as soon as possible. As to the facts, attached please find a certification by Richard Nolan Townsend, North America Regional President, Rare Disease Business Unit, attesting that the information provided in this letter is true and correct and represents a complete description of the facts regarding the questions identified in your letter.

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Please do not hesitate to contact me if you have any questions or require additional information. We appreciate the OIG's consideration of this request and look forward to working with you on this matter.

Sincerely,

Jeffrey L. Handwerker

Signed Certification of Requestor

With knowledge of the penalties for false statements provided by 18 U.S.C. § 1001 and with knowledge that this request for an advisory opinion is being submitted to the Department of Health and Human Services, I certify that all of the information provided in this response to OIG's request for follow-up information is true and correct, to the best of my knowledge and belief.

Dated: November 12, 2019

Pfizer Inc.

Richard Nolan Townsend
North America Regional President,
Rare Disease Business Unit